UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSSETTS

IN RE OCULAR THERAPEUTIX, INC. SECURITIES LITIGATION

This Document Relates To: All Actions

No. 1:17-cv-12288-GAO

CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

JURY TRIAL DEMANDED

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Lead Plaintiffs Kavita Mehta, Khaled Ramadan, William L. Stephens and Oleg Tkalych (collectively, "Plaintiffs"), individually and on behalf of all other persons similarly situated, by their undersigned attorneys, for their complaint against Ocular Therapeutix, Inc. ("Ocular" or the "Company"), Amarpreet Sawhney, George Migausky, Andrew Hurley and Eric Ankerud (collectively, "Defendants"), allege the following based upon personal knowledge as to themselves and their own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through their attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Ocular, analysts' reports and advisories about the Company, consultation with experts, and information readily obtainable on the Internet. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. INTRODUCTION

1. This is a federal securities class action (the "Action") on behalf of a class (the "Class") of investors who purchased or otherwise acquired Ocular securities between March 10, 2016 through July 11, 2017, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officers.

2. Ocular, a biopharmaceutical company, was founded in 2006 and is headquartered in Bedford, Massachusetts. The Company's stock trades on the NASDAQ stock exchange ("NASDAQ") under the ticker symbol "OCUL."

3. Ocular focuses on the development and commercialization of therapies for diseases and conditions of the eye using its proprietary hydrogel technology. The Company's lead product is DEXTENZA, which during the Class Period was in a Phase III clinical trial for the treatment of post-surgical pain and inflammation and in a Phase II clinical trial for the treatment of inflammatory dry eye disease. Prior to the Class Period, in September 2015, Ocular submitted a new drug application ("NDA") to the U.S. Food & Drug Administration ("FDA") in which it sought FDA approval of DEXTENZA for treatment of ocular pain following ophthalmic surgery.

4. During the Class Period, Ocular repeatedly and knowingly misled investors about the problems its manufacturing operations faced and about the impact those problems were likely to have on the FDA's approval of DEXTENZA.

5. In February 2016, the FDA inspected Ocular's manufacturing facility and identified numerous major problems with Ocular's manufacturing operations. For example, the inspector noted that the Company's analyses were not properly documented, that its sampling procedures did not ensure representativeness, that the Company's manufacturing procedures were inadequate to ensure the consistency of the drug mixture, and that the Company did not document rejections of batches or evaluate the issues leading to those rejections. The report of this inspection, a "Form 483," was given directly to the management of the Company, including the CEO, Defendant Sawhney, and made clear that the Company was not close to being in compliance with the FDA's standards for current good manufacturing practices or "cGMP," and that the Company would have to resolve major issues prior to obtaining FDA approval to manufacture DEXTENZA.

6. Rather than inform the public of the major problems documented in the Form 483 and their obvious implications for the Company, the Company affirmatively misrepresented only weeks later that it was in compliance with cGMP and downplayed the significance of the Form 483 in its public filings. Following the inspection, the FDA rejected Ocular's application for approval of DEXTENZA, and the Company's stock dropped.

7. The Company quickly resubmitted its application for FDA approval of DEXTENZA, and in April and May of 2017, the FDA again inspected Ocular's manufacturing facility. Again, the FDA found major problems with Ocular's manufacturing operations, and issued a new Form 483 identifying these problems, including problems similar to those that the FDA had previously identified that nevertheless had not been resolved or had become worse since the prior inspection. For example, Ocular's poor practices relating to documenting and resolving product rejections had only become worse, as the FDA found that more than 40% of product lots that were released for commercial use contained unknown particulate matter that included aluminum. Ocular had failed to investigate the nature of this particulate matter prior to releasing the product for use in human subjects, and had failed even to establish thresholds for the amount of particulate matter in the product that would constitute a critical defect. Likewise, the Company had failed to establish appropriate procedures to ensure the consistent preparation of its product. The Form 483 expressly noted that Ocular's quality control unit did not have the proper oversight "for batch initiation and execution of GMP batches," and had not ensured adequate training of facility employees.

8. After Defendant Sawhney and the Company received this Form 483, Defendants once again declined to inform the investing public about the grave problems the Company faced as identified in the Form. Instead, the Company continued to assure investors that it was in

compliance with cGMP, and continued to downplay the significance of the Form 483 and its implications for the FDA's approval of DEXTEZA.

9. On July 6, 2017, shortly before the end of the trading day, the website *Seeking Alpha* published an article entitled "Ocular: A Poke In The Eye," reporting, in part, that the Company's management had misled Ocular investors regarding ongoing manufacturing issues and downplayed the significance of U.S. Food and Drug Administration ("FDA") communications regarding these issues. On that same day, STAT published an article on the Company asserting that DEXTENZA could be rejected by the FDA because of product contamination, including aluminum, found by an FDA inspector during a visit to the company's manufacturing facility.

10. On this news, Ocular's share price fell $3.06, or over 30%, over two trading days, to close at $7.12 on July 7, 2017.

11. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiffs and other Class members have suffered significant losses and damages.

II. JURISDICTION AND VENUE

12. The claims asserted herein arise under and pursuant to §§ 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and § 27 of the Exchange Act.

14. Venue is proper in this Judicial District pursuant to § 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). The Company conducts business and a significant portion of Defendants' actions and subsequent damages took place within this District.

15. In connection with the acts, conduct and other wrongs alleged in this Complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

III. PARTIES

16. Plaintiffs, as set forth in their previously filed Certifications (incorporated here by reference), acquired Ocular securities at artificially inflated prices during the Class Period and were damaged upon the corrective disclosures alleged in this complaint.

17. Defendant Ocular is incorporated in Delaware, with principal executive offices located at 34 Crosby Drive, Suite 105, Bedford, Massachusetts 01730. The Company is registered to do business in New Jersey. Ocular's shares trade on the NASDAQ under the ticker symbol "OCUL."

18. Defendant Amarpreet Sawhney ("Sawhney") has served at all relevant times as the Company's Chief Executive Officer ("CEO"), Chairman, and President.

19. Defendant George V. Migausky ("Migausky") has served at all relevant times as the Company's Chief Financial Officer ("CFO").

20. Defendant Andrew Hurley ("Hurley") has served at all relevant times as the Company's Chief Commercial Officer.

21. Defendant Eric Ankerud ("Ankerud") was the Company's Executive Vice President of Regulatory, Quality, and Compliance throughout the Class Period.

22. Defendants Ankerud, Hurley, Migausky and Sawhney are sometimes referred to herein as the "Individual Defendants."

IV. SUBSTANTIVE ALLEGATIONS

A. Background

23. Ocular is a biopharmaceutical company that focuses on the development and commercialization of therapies for diseases and conditions of the eye. The Company's lead product candidate is DEXTENZA, which during the Class Period was in Phase III clinical trial for the treatment of post-surgical pain and inflammation, allergic conjunctivitis; and in Phase II clinical trial for the treatment of inflammatory dry eye disease.

24. DEXTENZA is a medical implant (a "plug") designed to be inserted into the canaliculi of the eyes' tear ducts (*i.e.*, an "intracanalicular insert"). After insertion, the product releases its active pharmaceutical ingredient, the corticosteroid dexamethasone, in Ocular's proprietary "hydrogel" onto the surface of the eye. The hydrogel is designed to provide sustained delivery of its active ingredient to the eye and to act as an ocular tissue sealant. Accordingly, DEXTENZA may be described as a combination product—as both a drug and the delivery device for that drug.

25. Ocular's manufacturing facility is located in Bedford, Massachusetts. Ocular's product candidates, including DEXTENZA, require sterile drug manufacturing processes, so Ocular's manufacturing facility is subject to the FDA's regulations governing sterile drug manufacturing.

26. At all relevant times, Ocular has misrepresented to investors that it manufactures its product using "current good manufacturing practices" ("GMP" or "CGMP" or "cGMP").

27. The cGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. Section 21 of the Code of Federal Regulations contains most regulations pertaining to cGMP. The regulations make sure that a product is safe for use, that it has the ingredients and

strength it claims to have, and that the product is manufactured in accordance with certain quality control standards relating to, for example, the consistency and purity of the product. The Company itself has recognized that it "must comply with federal, state and foreign regulations, including quality assurance standards applicable to medical device and drug manufacturers, such as cGMP, which is enforced by the FDA through its facilities inspection program and by similar regulatory authorities in other jurisdictions where we do business. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation." *See* 2015 Form 10-K dated March 10, 2016.

28. The approval process for new drug and device applications includes a review of the manufacturer's compliance with the cGMP. FDA inspectors and reviewers determine whether the firm has the necessary facilities, equipment, and skills to manufacture the new drug for which it has applied for approval. Decisions regarding compliance with cGMP regulations are based upon inspection of the facilities, sample analyses, review of the regulatory file, and compliance history of the firm.

29. Form FDA 483 is a form used by the FDA to document and communicate objectionable conditions and practices discovered during inspection of drug manufacturing facilities that render the facilities out of compliance with cGMP. Accordingly, receipt of a Form 483 identifying serious problems in the conditions or practices of a company strongly indicates to the company and to investors that the company is not in compliance with cGMP. A company that has received a Form 483 identifying serious problems in its conditions or practices relating to its manufacture of a drug reasonably may expect that such problems must be resolved prior to obtaining approval by the FDA to manufacture and market the drug.[1]

[1] Ocular received its first Form 483 in March 2015, after the FDA conducted an inspection of the Company's manufacturing facility during which the FDA identified certain deficiencies that were documented to the Company

B. The FDA Identified Serious Deficiencies in the Company's Manufacturing and Quality Control Processes in February 2016

30. In September 2015, Ocular submitted a new drug application ("NDA") to the FDA in which its sought FDA approval of DEXTENZA for treatment of ocular pain following ophthalmic surgery. The FDA accepted the NDA for filing and established a target date for action on the application under the Prescription Drug User Fee Act ("PDUFA") of July 24, 2016.

31. In February 2016, as part of its ongoing review of Ocular's NDA for DEXTENZA, the FDA conducted another pre-approval inspection of the Company's manufacturing operations. The inspection team included investigators Edmund Mrak and Jonathan Matrisciano, reviewers Vidya Pai and Chunchun Zhang, and chemist Aditi Thakur. On February 11, 2016, after its inspection, the inspection team issued Ocular a Form 483 (incorporated here by reference, the "February 2016 Form 483") on which it listed ten "observations," or notes concerning areas where the team found Ocular's manufacturing operations not to be in compliance with FDA regulations, including those pertaining to cGMP.

32. The inspectional observations detailed in the February 2016 Form 483 were very serious. The observations made clear that Ocular's manufacturing processes and procedures were not in compliance with cGMP and would need significant and lengthy corrections in order to meet minimum cGMP requirements.[2] The nature of these observations made very likely—if

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in a Form 483 (the "March 2015 Form 483"). The Company did not inform investors of the outcome of this inspection or of its receipt of the March 2015 Form 483 at the time, however. Instead, the Company disclosed for the first time in its Form 10-Q dated May 10, 2016, that "[f]ollowing an inspection by the FDA in March 2015, . . . we received an FDA Form 483 containing an inspectional observation relating to inadequate procedures for documenting follow-up information pertinent to the investigation of complaints and for evaluation of complaints for adverse event reporting. We submitted our response, which was accepted by the FDA, and updated our procedures."

[2] Specifically, at a minimum, Observation 1 documented the Company's non-compliance with 21 C.F.R. § 211.180 and 21 C.F.R. § 211.194(a); Observation 2 documented the Company's non-compliance with 21 C.F.R. § 211.160(b) and (b)(1); Observation 3 documented the Company's non-compliance with 21 C.F.R. § 211.100, and Observation 3.D also documented the Company's non-compliance with 21 C.F.R. § 211.180(e); Observation 4 documented the Company's non-compliance with 21 C.F.R. § 211.103; Observation 5 documented the Company's non-compliance with 21 C.F.R. § 211.101(a); Observation 6 documented

not certain—that Ocular would be unable timely to remedy the concerns prior to the FDA's target action date for the NDA of July 2016, and that consequently, the FDA would issue a complete response letter ("CRL") rejecting Ocular's NDA for DEXTENZA in the form it was originally submitted.

33. Observation 1 noted that Ocular's documentation of the analysis it submitted in connection with its NDA was deficient because Ocular had retained only reprocessed data from its testing, and had included only reprocessed data in its analysis. In particular, the inspection team found that "printed HPLC chromatograms and integration results for dose content uniformity and purity were discarded . . . and only the reprocessed data was printed and retained." Failure to retain such records constitutes a serious data integrity breach. A company must use original testing data in conducting the analyses on which it bases its NDA, and the company must retain all such original testing data for FDA inspectors to permit them to verify the accuracy of the analyses the company has submitted to the FDA. Observation 1 in effect required the Company to redo its analysis of DEXTENZA.

34. Observation 1.B.1 was likewise highly problematic. The inspectors noted that in reviewing the reprocessed data, the data revealed "a failure to include the area of a typical peak of unknown impurity" at a given retention time "in the total area and content of unknown impurities." That is, the Company's reprocessed chromatogram data produced during the company's analysis of DEXTENZA's purity showed that the Company had failed to incorporate data relating to a particular, regularly occurring impurity into its overall analysis of the impurities in DEXTENZA.

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the Company's non-compliance with 21 C.F.R. § 211.160(b) and 21 C.F.R. § 211.165; Observation 7 documented the Company's non-compliance with 21 C.F.R. § 211.46; Observation 8 documented the Company's non-compliance with 21 C.F.R. § 211.111; and Observation 9 documented the Company's non-compliance with 21 C.F.R. § 211.28(c); Observation 10 documented the Company's non-compliance with 21 C.F.R. § 211.58.

35. Observation 1.D further noted that the Company even lacked "written procedures to clearly specify how manual integration of chromatograms is performed." Without such written procedures, the Company—and the FDA—had no way of knowing that the Company was performing calculations relating to its analysis of DEXTENZA in a consistent manner to obtain reproducible and reliable results.

36. Observation 2 noted that the Company's procedure for sampling drug products for conformity with written specifications did not ensure that the samples were representative. The Company's procedure called for taking "random" samples of a finished production lot, but that procedure does not ensure that the samples are representative.

37. Observation 3 similarly made clear that the Company's basic manufacturing procedures were wholly inadequate. Observation 3 stated that "[c]ontrol procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product." Indeed, the control procedures failed to ensure even the most basic elements of the drug preparation, including that the bulk preparation of the drug was *adequately mixed* to attain product consistency.

38. Observation 3.D stated that the company "did not characterize and trend rejects produced during inspection of drug product." That is, the Company did not document batches that were potentially defective or investigate the reasons why they were potentially defective. The Company's procedures potentially missed detection of voids (*i.e.*, bubbles) and other defects, including defects such as particulate contamination, in the drug product. It is necessary to identify, characterize, and trend rejects in order to reduce the occurrence of such rejects in the future.

39. The remaining observations were equally damning. Observation 4, while also redacted, made clear that certain discrepancies in its yields demonstrated a "lack of accountability for the full formulated batch quantity, quality, and finished drug yield." Observation 6 stated, in general terms, that "Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity." Observations 7 and 8 stated that the Company even lacked adequate equipment and procedures to control the temperature of its products and production environment to prevent product contamination and the growth of microorganisms. Additionally, the Company had failed to establish time limits for how long the product could safely be stored and at what temperature. Observations 9 and 10 noted that unauthorized persons could easily gain entry and access to the Company's manufacturing operations, and that the manufacturing facility itself was in a state of disrepair.

40. In short, the inspectional observations appearing on the February 2016 Form 483, had they been made public at the time, would have made clear to any reasonable reader that the Company had to make numerous significant changes to its manufacturing operations, at great expense and delay, in order to gain FDA approval for DEXTENZA.

C. Defendants Misled Investors by Misrepresenting the Company's cGMP Compliance and by Seriously Downplaying the FDA's Concerns

41. Rather than informing investors of the grave difficulties and obvious delay the Company faced in getting its manufacturing operations back on track, Defendants expressly told investors that its manufacturing operations continued to be cGMP. Defendants downplayed and misrepresented the results of the FDA's February 11, 2016 inspection by failing to tell the whole truth about the inspectional observations the Company had received.

42. On March 10, 2016, Ocular filed its Annual Report on Form 10-K for the year 2015 with the SEC (the "2015 Form 10-K"). Even though Ocular had received the Form 483 containing damning inspectional observations—observations that would have made any reasonable recipient aware that the Company was nowhere near meeting regulatory standards for cGMP—Ocular nevertheless flatly told investors:

> We fabricate devices and drug depot products . . . for all our therapeutic product candidates using current good manufacturing practices, or cGMP, at our multi-product facility located in Bedford, Massachusetts.

43. In its 2015 Form 10-K, Ocular likewise downplayed and misrepresented the results of the FDA's February 11, 2016 inspection of its manufacturing operations by failing to tell the whole truth about the February 2016 Form 483 inspectional observations:

> As a result of this inspection, we received an FDA Form 483 containing inspectional observations focused on process controls, analytical testing and physical security procedures related to manufacture of our drug product for stability and commercial production purposes. We addressed some observations before the inspection was closed and responded to the FDA with a corrective action plan to complete the inspection process.

44. Importantly, while Defendants acknowledged having received the February 2016 Form 483, they concealed and significantly downplayed the magnitude and significance of the inspectional observations Ocular had received: these inspectional observations would require Ocular to redo a significant part of its product testing and resubmit its analysis for the NDA for DEXTENZA, revise key manufacturing procedures, such as those related to product testing and sampling, and create new procedures to cover numerous basic concerns the Company apparently had not previously considered, such as temperature control for its products and production environment.

D. The FDA's Concerns as Expressed in the February 2016 Form 483 Resulted in Rejection of the NDA in July 2016

45. In July 2016, Ocular received a CRL from the FDA regarding its NDA for DEXTENZA in which the FDA rejected Ocular's application. While the Company did not make the CRL itself public, Ocular issued a press release and stated that "[t]he concerns raised by the FDA pertain to deficiencies in manufacturing process and controls identified during a pre-NDA approval inspection of the Ocular Therapeutix manufacturing facility." In other words, in the CRL, the FDA cited as reasons for the rejection the deficiencies in manufacturing processes that had been raised in the February 2016 Form 483. When the Company announced in its press release on July 25, 2016 that it had received the CRL, and so first revealed to investors that the inspectional observations in the Form 483 had been serious enough to cause the FDA to reject Ocular's NDA, Ocular's share price dropped significantly, as detailed below in Part VI.

E. Defendants Resubmitted the NDA, Which Failed to Address Fully the FDA's Concerns

46. On January 23, 2017, the Company announced that it had resubmitted its NDA for DEXTENZA. Remarkably, the Company resubmitted its application even though it knew that this NDA resubmission would not meet FDA standards. A confidential witness ("CW") had a direct conversation with Defendant Ankerud in late 2016 or early 2017, prior to the Company's NDA resubmission, in which Ankerud expressly acknowledged that he and the Company knew Ocular would be including batch records in the NDA resubmission that would not meet FDA standards. CW was employed by Ocular in its Bedford, Massachusetts facility as a Regulatory Affairs Project Manager from November 1, 2016 until approximately the end of February 2017 or early March 2017. CW reported to Director of Regulatory Affairs Elizabeth Fenna, who reported directly to Defendant Ankerud. Ankerud was hired as a full-time employee in Regulatory Affairs to work on the NDA resubmission for DEXTENZA.

47. On February 22, 2017, the Company announced that the FDA had accepted for review its NDA resubmission. The FDA determined that the Company's NDA resubmission was a Complete Response and designated the NDA resubmission as a class 2, or major, review with a PDUFA target action date of July 19, 2017 (the "PDUFA Action Date")

F. The FDA Conducted a Re-Inspection in May 2017; Ocular Continued to Mislead Investors about Its Compliance with cGMP Thereafter

48. During the period spanning April 24, 2017 to May 4, 2017, the FDA made additional visits to Ocular's manufacturing facilities to reinspect the facilities as part of its review of Ocular's NDA for DEXTENZA. The inspection team was led by investigator Nealie C. Newberger. Following this series of inspections, on May 4, 2017, the FDA issued another Form 483 (incorporated here by reference, the "May 2017 Form 483") that identified six inspectional observations noting areas where the inspection team had found Ocular's manufacturing operations not to be in compliance with FDA regulations, including, again, cGMP.[3]

49. These inspectional observations were as damning as those listed in the FDA's February 2016 Form 483—indeed, several of the observations *repeated* or *expanded on* concerns first raised in the February 2016 Form 483.

50. Observation 1 revealed the FDA's bombshell finding that unknown and uninvestigated particulate matter had been found in 10 of 23 lots (more than 43%) Ocular had manufactured from February 2016 to May 2017—*i.e.*, during the time *following* the February 2016 inspection, when manufacturing conditions should have been *improving* in response to the

[3] Specifically, at a minimum, Observation 1 documented the Company's non-compliance with 21 C.F.R. § 210.1(b) and 21 C.F.R. § 211.22(a); Observation 2 documented the Company's non-compliance with 21 C.F.R. § 211.22(d) and 21 C.F.R. § 211.100; Observation 3 documented the Company's non-compliance with 21 C.F.R. § 211.10; Observation 4 documented the Company's non-compliance with 21 C.F.R. § 211.188 and 21 C.F.R. § 211.22(d); Observation 5 documented the Company's non-compliance with 21 C.F.R. § 211.160(b) and 21 C.F.R. § 211.165; and Observation 6 documented the Company's non-compliance with 21 C.F.R. § 211.25(a).

FDA's previously voiced concerns over manufacturing and quality control issues. The remaining lots had been scrapped altogether prior to inspection, and so may also have contained particulate matter. The Company had determined prior to April 28, 2017 (and so prior to the inspection), yet had not publicly revealed, that the particulate matter in the lots (including lots release for intended commercial use on January 12, 2017), appeared inclusive of aluminum. Aluminum is toxic and harmful to humans if consumed or absorbed.

51. Equally troubling, Observation 1 noted that these lots found to have contained unknown particulate matter were released for intended commercial use, including on January 12, 2017. As the particulate matter observed in these lots was unknown, the matter could have contained other toxic substances harmful to humans. The Company had failed altogether to investigate the nature of this particulate matter until April 28, 2017 (*i.e.*, during the course of the FDA's site inspection), when the Company noted that the particulate matter appeared inclusive of aluminum. Particulates were not even logged as product defects prior to February 2016.

52. Closely related to Observation 1, Observation 2 noted that the Company had failed to define what constituted critical defects in its products, including but not limited to defects such as particulate matter found within the product. On January 12, 2017, the Company had released three lots intended for commercial use without critical defect limits established for the products that were being released. In these three lots, 224 plugs, 45 plugs, and 37 plugs, respectively, had been rejected due to unknown particulate matter. The FDA observed that other lots were released for human use in clinical trials without critical defect limits even having been established.

53. Observation 3 showed unequivocally that the Company had failed to resolve certain key deficiencies the FDA had observed in its manufacturing processes in February 2016.

Observation 3 noted in general that, "There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." Then Observation 3 noted specifically that the Company "lacked documentation to show that [its] product could consistently meet specifications." Importantly, the Observation noted that Ocular "ha[d] not systematically evaluated the lots manufactured from February 2016 to [May 2017, the date of the Form 483]."

54. Observation 4 likewise expanded on the observations from the February 2016 Form 483, and detailed further blatant inadequacies in Ocular's controls, including its quality control unit ("QCU"). Observation 4 noted in general that "[t]he responsibilities and procedures applicable to the quality control unit are not in writing." Observation 4 also made unmistakably clear to Ocular that the FDA found its manufacturing operations not to be in compliance with cGMP when it stated, "[y]our QCU does not have the proper oversight for batch initiation and execution of GMP batches."

55. Observation 5 repeated Observation 6 from the February 11, 2016 Form 483. Observation 5 stated, "Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity." In particular, Ocular had failed to develop adequate methods to test the degradation and purity of DEXTENZA. For example, Ocular lacked methods adequate to evaluate the stability of DEXTENZA because it failed to include a forced degradation study in its stability testing program.

56. Observation 6 from the May 2017 Form 483 made clear that the Company's training procedures were likewise inadequate.

57. The day following its receipt of the May 2017 Form 483, Ocular released its financial results for the first quarter of 2017 in its May 5, 2017 Quarterly Report on Form 10-Q and held a conference call for investors to discuss its disclosures and its operations.

58. During the conference call, Defendant Sawhney acknowledged the FDA's recent inspection and the Company's receipt of the May 2017 Form 483. When the Company announced that it had received a second Form 483, and so partly revealed that it had misrepresented the seriousness of the problems identified in the February 2016 Form 483 and its ability to cure those problems, the price of Ocular's stock dropped significantly, as detailed below in Section IV.

59. However, Sawhney failed to reveal the numerous grave deficiencies in Ocular's manufacturing operations noted in the Observations in the May 4, 2017 Form 483, and instead again misleadingly downplayed the inspection results. On the May 5, 2017 conference call, Defendant Ankerud stated that the Company expected to be able to resolve the problems identified in the May 5, 2017 Form 483 "in a timely manner" (*i.e.*, by the July 19, 2017 PDUFA Action Date). In their misleading remarks, Defendants Sawhney and Ankerud omitted the numerous damning observations in the May 4, 2017 Form 483, as detailed below in Part V.

60. On July 6, 2017, shortly before the end of the trading day, the website *Seeking Alpha* published an article in which it made public, for the first time, the February 11, 2016 and May 4, 2017 Forms 483. The article also described the content of the Forms 483 and opined that the Forms made obvious even to lay readers that the company had serious manufacturing problems:

> Even a layperson reading this [second Form 483] can tell that the company is having serious manufacturing issues, and their whole approach to manufacturing and patient safety is highly questionable. What's more troubling is that either

> management doesn't fully understand the letter, or they have been misleading investors. Both are bad.

61. The article went on to note that the Forms 483 Ocular had received contained observations in the first that were repeated in the second, and observations in the second that were even worse than those in the first. For example, the article noted that Observation 6 of the February 11, 2016 Form 483 and Observation 5 of the May 4, 2017 Form 483 both stated that, "Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity strength, quality and purity." The article likewise noted that Observation 3 of the May 4, 2017 Forms 483 meant "[i]n plain English" that "OCUL still doesn't know how to make their product consistently."

62. The article recognized that the Company plainly was misleading investors in stating that their manufacturing was "in a fully developed mode" when the May 4, 2017 Form 483 made clear that Ocular's manufacturing operations were far from obtaining approval and needed significant revisions. The article noted that Observation 1 of the May 4, 2017 Form 483, "[i]n plain English" meant "that more than 50% of lots manufactured by OCUL contain bad product." The article summarized Ocular's situation in light of the May 4, 2017 Form 483:

> The reality is, IF Dextenza is possible to manufacture on a mass scale, something which hasn't been done before, OCUL needs to revamp their entire process from the ground up, which can take years to do. They need to use the proper scientific tools and procedures.

63. When the public learned of the seriousness of the manufacturing deficiencies in Ocular's operations, as identified in the Forms 483, which Ocular had hidden, the price of Ocular's stock again dropped significantly.

64. On July 12, 2017, the Company received a second CRL from the FDA rejecting for the second time its NDA for DEXTENZA for the treatment of post-surgical ocular pain, and

again, Ocular's stock dropped significantly as the market learned of this new manifestation of the seriousness of the FDA's Observations, which the Company had repeatedly downplayed.

65. On December 15, 2017, the Company received a subpoena from the SEC that indicated that the SEC is investigating the Company for its practices relating to DEXTENZA. As the Company admitted in a December 22, 2017 press release, the SEC subpoena requests, "documents and information concerning DEXTENZA™ (dexamethasone insert) 0.4mg, including related communications with the FDA, investors and others."

66. As of the date of this Complaint, Ocular's NDA for DEXTENZA still has yet to be approved. Ocular has stated publicly that it plans to resubmit its NDA for DEXTENZA for the treatment of post-surgical ocular pain in the first half of 2018.

V. DEFENDANTS' FALSE AND MISLEADING STATEMENTS

A. Defendants' False and Misleading Statements in 2016

67. On March 10, 2016, Ocular filed its Annual Report on Form 10-K (the "2016 10-K") in which the Company stated in part:

> We fabricate devices and drug depot products for use in our clinical trials, research and development and commercial efforts for all of our therapeutic product candidates using current good manufacturing practices, or cGMP, at our multi-product facility located in Bedford, Massachusetts.

68. The statements referenced in ¶ 67 were materially false and/or misleading because: (i) Ocular did not use current Good Manufacturing Practices at its manufacturing facility in Bedford, Massachusetts; (ii) Ocular omitted material negative facts about Ocular's manufacturing processes, control procedures, recordkeeping, and other aspects of Ocular's manufacturing; and (iii) in omitting material negative facts about Ocular's manufacturing practices (including, for example, that Ocular had not systematically evaluated lots produced at its manufacturing facility from February 2016 to the date of the statement), the statements

concealed the risk that Ocular's manufacturing processes would produce and release a material amount of bad product.

69. Also on November 9, 2016, the Company held an earnings conference call with investors, during which Defendant Sawhney stated in part:

> I am pleased to report that we have had productive discussions with the FDA over the past several months. *We believe we have taken the appropriate steps to address the manufacturing related items raised by the FDA*, although the FDA will make its determination after we resubmit our NDA. As a reminder, in July we received a CRL, or complete response letter, relating to certain manufacturing processes on control deficiencies, and subsequently received a letter from the New England district office providing additional details as to the outstanding deficiencies related to their pre-NDA approval inspection of the Ocular Therapeutix manufacturing facility.
>
> Among these was an observation related to the proposed process for identifying identity testing of an incoming inert gas component used in the DEXTENZA manufacturing process. The district office letter also requested that we submit a formal report providing evidence that migration to automatic integration of analytical testing has been completed.
>
> (Emphasis added.)

70. The statements referenced in ¶ 69 were materially false and/or misleading because: (i) the Company had not taken appropriate steps to address all the manufacturing related items raised by the FDA; (ii) Ocular omitted material negative facts about Ocular's manufacturing processes, control procedures, recordkeeping, and other aspects of Ocular's manufacturing; and (iii) in omitting material negative facts about Ocular's manufacturing practices (including, for example, that Ocular had not systematically evaluated lots produced at its manufacturing facility from February 2016 to the date of the statement), the statements concealed the risk that Ocular's manufacturing processes would produce and release a material amount of bad product.

71. On the November 9, 2016 earnings conference call, Defendant Sawhney also stated in part:

> But whether or not re-inspection is required, is a determination that [CDER] will make. And they just said that we'll get back to you in 30 days after your resubmission to inform you. That's so—we really can't get more guidance or can't give more guidance on that. *I think it's important to realize that this is a matter of when not if type of a thing, we've adequately we think addressed the issues that they've raised. And communicated our plans to them and they seem in broad agreement with the plans that we have communicated.*
>
> But until they kind of review the resubmission, they will not be in a position of giving any further guidance. So, when we do that, let's say that that were by the end of the year December we submit. In January they would let us know whether it's one more month left or five more months left.
>
> (Emphasis added.)

72. The statements referenced in ¶ 71 were materially false and/or misleading because: (i) the Company had not adequately addressed the issues raised by the FDA; (ii) the Company omitted material negative facts about Ocular's manufacturing processes, control procedures, recordkeeping, and other aspects of Ocular's manufacturing that suggested that the Company had not adequately addressed the issues raised by the FDA and was highly unlikely to obtain FDA approval for DEXTENZA.

B. Defendants' False and Misleading Statements in 2017

73. On March 10, 2017, Ocular filed its Annual Report on Form 10-K (the "2017 10-K") in which the Company stated in part:

> We fabricate devices and drug insert and depot products for use in our clinical trials, research and development and commercial efforts for all of our therapeutic product candidates using current Good Manufacturing Practices, or cGMP, at our multi-product facility located in Bedford, Massachusetts.

74. The statements referenced in ¶ 73 were materially false and/or misleading because: (i) Ocular did not use current Good Manufacturing Practices at its manufacturing facility in Bedford, Massachusetts; (ii) Ocular omitted material negative facts about Ocular's manufacturing processes, control procedures, recordkeeping, and other aspects of Ocular's manufacturing; (iii) in omitting material negative facts about Ocular's manufacturing practices

(including, for example, that Ocular had not systematically evaluated lots produced at its manufacturing facility from February 2016 to the date of the statement), the statements concealed the risk that Ocular's manufacturing processes would produce and release a material amount of bad product.

75. On May 5, 2017, the Company held an earnings conference call with investors, during which Defendant Ankerud stated the following regarding Form 483:

> FDA completed the re-inspection of our facility as part of the NDA review late yesterday afternoon. As Amar mentioned, 4[8]3 was issued. We were pleased during the re-inspection that the FDA investigator was able to confirm our corrective action plan from prior observations, and indicated that there was no further follow-up necessary to close out those issues. This was a new investigator not the same investigator from prior inspections, and their primary focus in the 4[8]3 relates to a particula[te] matter issue as part of our manufacturing process. The issue relates primarily to completion of an investigation that we have underway in regard to the particular[te] matter solidifying specifications for in process, 100% visual inspection of our inserts, as well as enhancing our operator training. *We feel quite comfortable that we have the situation under control and we are preparing responses to the 4[8]3 as of this morning in anticipation of responding within 15 calendar days to the agency.* In addition to the particular matter issue, FDA raised a couple of observations in regard to analytical method, testing to be completed, as well as some other issue related to quality oversight of batch records. *So in summary, we believe that each of the observations raised by FDA during this continuous improvement review of our fully developed manufacturing process are handled well and will be resolved in our response to FDA.* We're also pleased that the collaborative nature of our NDA review has continued between the various offices of FDA, and *we're marching toward that PDUFA date and expect that we can resolve the 4[8]3 issues in a timely manner.*
>
> (Emphasis added.)

76. The statements referenced in ¶ 75 were materially false and/or misleading because: (i) the Company's "manufacturing process" was not "fully developed," as the Company still faced very significant obstacles in developing manufacturing processes and controls so as to manufacture its products consistently and according to cGMP; (ii) while Ocular stated that the Company expected to be able to resolve the problems identified in the May 5, 2017 Form 483 "in a timely manner" (*i.e.*, by the July 19, 2017 PDUFA date), Ocular failed to

inform investors that the Form 483 raised issues that the Company was highly unlikely to be able to resolve before July 19, 2017; (iii) Defendants' statement mentioned certain problems identified in the Form 483, but omitted mention of even greater problems identified in that Form.

77. Also on the May 5, 2017 earnings call, Defendant Ankerud stated in part:

> I think there is two important issues to recognize. The first is that from the prior preapproval inspection, FDA issued a 4[8]3. We resolve those issues, close those issues with the district office and during this re-inspection the new investigator is responsible for confirming that we have implemented what was said in our responses. And the investigator went through each of our responses and confirm that we had properly and appropriately implemented those actions. *So I think that's a strong sign that the manufacturing process has moved forward significantly, and is in a fully developed mode.*
>
> (Emphasis added.)

78. The statements referenced in ¶ 77 were materially false and/or misleading because: (i) the Company's "manufacturing process" was not "fully developed," as the Company still faced very significant obstacles in developing manufacturing processes and controls so as to manufacture its products consistently and according to cGMP; and (ii) the Company failed to disclose the very serious problems identified in the Form 483 or to characterize the problems identified in the Form 483 as very serious.

79. On the same earnings call, Defendant Sawhney discussed with analysts Form 483, stating in part:

> Andrew Berens
>
> Okay. *Is there anything in their observations that you think could delay the action date specifically?*
>
> Amar Sawhney
>
> *Nothing that we can currently see.* I think these—as you know, probably 90% plus inspections have 483. The question is one of the nature of the issues in the 483, we think these are resolvable issues, and we have responses. Some already prepared and some being prepared to address them in a timely fashion.

(Emphasis added).

80. The statements by Sawhney referenced in ¶ 79 were materially false and/or misleading because the Form 483 raised issues that the Company was highly unlikely to be able to resolve before July 19, 2017.

VI. LOSS CAUSATION

81. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiffs and the Class.

82. Throughout the Class Period, the price of the Company's securities was artificially inflated as a result of Defendants' materially false and misleading statements and omissions identified herein.

83. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

A. July 25, 2016

84. On July 25, 2016, Ocular issued a press release titled, "Ocular Therapeutix™ Receives Complete Response Letter from FDA for its NDA for DEXTENZA™ for the Treatment of Post-Surgical Ocular Pain." In the press release, the Company announced that it had received a complete response letter from the FDA refusing to grant approval of Ocular's NDA for DEXTENZA. The press release stated that the refusal was based on "deficiencies in manufacturing process and controls identified during a pre-NDA approval inspection of the Ocular Therapeutix manufacturing facility."

85. On this news, Ocular's share price fell $0.75, or 14.51%, to close at $4.42 on July 25, 2016.

B. May 5, 2017

86. On May 5, 2017, Ocular issued a press release titled, "Ocular Therapeutix™ Reports First Quarter 2017 Financial Results." In the press release, Ocular revealed that the FDA had completed inspections of its manufacturing facility and had issued a new Form 483 detailing deficiencies in Ocular's manufacturing. The Company stated, "Following a re-inspection of manufacturing operations by the FDA which was completed earlier this week, Ocular Therapeutix received an FDA Form 483 containing inspectional observations focused on procedures for manufacturing processes and analytical testing, related to manufacture of drug product for commercial production."

87. On this news, Ocular's share price fell $1.47, or 16.15%, to close at $7.63 on May 5, 2017.

C. July 6-7, 2017

88. On July 6, 2017, shortly before the end of the trading day, the website *Seeking Alpha* published an article entitled "Ocular: A Poke In The Eye," reporting, in part, that the Company's management had misled Ocular investors regarding ongoing manufacturing issues and downplayed the significance of FDA communications regarding these issues. The article included links to the February 11, 2016 Form 483 and May 5, 2016 Form 483, and so made these documents public for the first time. The two Forms 483 detailed the numerous inspectional observations that the FDA had made during its 2016 and 2017 inspections, such as identifying the presence of unknown particulate matter in a significant percentage of the Company's product batches that was inclusive of aluminum. The two Forms 483 revealed that the Company had misled the public as to the contents of the two Forms and the severity of the problems plaguing Ocular's manufacturing operations.

89. On this news, Ocular's share price fell $3.06, or 30.06%, over the next two trading days, to close at $7.12 on July 7, 2017.

D. July 12, 2017

90. On July 12, 2017, the Company issued a press release titled, "Ocular Therapeutix™ Receives Complete Response Letter from FDA for DEXTENZA™ NDA." The Company announced that it again had received a complete response letter from the FDA refusing a second time to grant approval of Ocular's NDA for DEXTENZA. The press release stated that the refusal was based on "deficiencies in manufacturing processes and analytical testing related to manufacture of drug product for commercial production identified during a pre-NDA approval inspection of the Ocular Therapeutix manufacturing facility that was completed in May 2017."

91. On this news, Ocular's share price fell $0.93, or 12.24%, to close at $6.67 on July 12, 2017.

92. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiffs and other Class members have suffered significant losses and damages.

VII. ADDITIONAL SCIENTER ALLEGATIONS

93. Ocular, Ankerud, Hurley, Migausky and Sawhney each knew of the false and misleading nature of the statements discussed above, or at a minimum was reckless for not knowing these matters.

94. Defendant Sawhney ("Sawhney") served at all relevant times as the Company's Chief Executive Officer ("CEO"), Chairman, and President.

95. Defendant George V. Migausky ("Migausky") served at all relevant times as the Company's Chief Financial Officer ("CFO").

96. Defendant Andrew Hurley ("Hurley") served at all relevant times as the Company's Chief Commercial Officer.

97. Defendant Eric Ankerud ("Ankerud") served as the Company's Executive Vice President of Regulatory, Quality, and Compliance throughout the Class Period.

98. Defendant Sawhney served as CEO of Ocular at all relevant times and was a Director of Ocular throughout the Class Period. As CEO, Sawhney was the head of Ocular's management and operations teams. Sawhney, by virtue of his responsibilities and activities as CEO and Director of the Company, was privy to all material information concerning the FDA's approval of DEXTENZA, including the results of the critical FDA inspections of Ocular's manufacturing facilities. In connection with the FDA's March 2015 facility inspections, Defendant Sawhney presented himself to FDA inspectors as "the most responsible person of the firm" and as having "overall responsibility of the firm," as documented in the FDA's March 2015 Establishment Inspection Report. Moreover, the February 11, 2016 and May 4, 2017 Forms 483 were addressed to, and sent directly to, Defendant Sawhney, so Defendant Sawhney was aware of the Observations detailed in those Forms 483.

99. Defendants Migausky served as CFO of Ocular at all relevant times and likewise served as a Director of Ocular throughout the Class Period. Migausky, as CFO, was privy to, and participated in, all matters directly impacting the financial health of Ocular, including the likelihood of the FDA's rejection of the NDA for DEXTENZA.

100. Defendant Hurley, who served as the Company's Chief Commercial Officer, likewise could not have failed to know about critical events impacting the commercial operations of the company, including the FDA's inspection of Ocular's manufacturing facility and the results of that inspection.

101. Finally, Defendant Ankerud, who served as the Company's Executive Vice President of Regulatory, Quality, and Compliance throughout the Class Period, could not have been unaware of the damning Observations included in the February 11, 2016 and May 4, 2017 Forms 483. The essence of Ankerud's job was to ensure that the Company's key drug candidate, DEXTENZA, and the manufacturing facility responsible for producing it, met applicable regulations, including cGMP. In connection with the FDA's inspections conducted in March 2015, Defendant Ankerud presented himself to the FDA as having primary responsibilities for: "clinical operations, regulatory affairs, quality assurance, customer complaints, and MDR submissions. Mr. Ankerud explained that he is the Management Representative and reports to Dr. Sawhney." The FDA's Establishment Inspection Report generated in connection with its March 2015 inspections further noted that Ocular management represented to the FDA that "in absence of the CEO, Mr. Ankerud was the most responsible person of the firm and was designated as the person to receive the FDA Form 483." During the Class Period, Ankerud's job focused on addressing the Observations identified in the February 11, 2016 and May 4, 2017 Forms 483. Moreover, to do his job, Ankerud must have been familiar with cGMP. Accordingly, Ankerud was award of the Observations, and was aware that Ocular's manufacturing operations did not conform to cGMP.

102. The core of Ocular's business is the manufacturing of its primary drug candidate, DEXTENZA. Ocular itself has labelled this drug its "lead candidate," and so admits the central importance of this drug to its business. Given the key importance of Ocular's ability to manufacture DEXTENZA to Ocular's business, strategy, and valuation, Defendants Ocular, Ankerud, Hurley, Migausky and Sawhney each had knowledge of all material information affecting DEXTENZA, and so had knowledge of all material hurdles relating to Ocular's

manufacturing of DEXTENZA, including the Observations noted in the February 11, 2016 and May 4, 2017 Forms 483.

103. The statements of CW likewise make clear that Ocular and the Individual Defendants were aware of the severity of the problems Ocular faced in manufacturing DEXTENZA using cGMP, and that its submissions to the FDA for approval of its manufacturing operations for DEXTENZA were highly unlikely to be approved. CW stated that he had a direct conversation with Defendant Ankerud in late 2016 or early 2017, prior to the Company's NDA resubmission, in which Ankerud acknowledged that the company knew it would be including batch records in the NDA resubmission that would not meet FDA standards.

104. Defendants Sawhney and Migausky each signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") for each SEC filing referenced in Part V above during their tenure as CEO and CFO. In these certifications, Sawhney and Migausky each certified that he had reviewed the SEC filings and determined that they contained no false or misleading statements or omissions.

105. In virtue of their high-level positions, Ankerud, Hurley, Migausky and Sawhney's knowledge may be imputed to Ocular.

VIII. CLASS ACTION ALLEGATIONS

106. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Ocular securities publicly traded on the NASDAQ during the Class Period (the "Class"), and were damaged upon the alleged corrective disclosure. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

107. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Ocular securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by the Company or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

108. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

109. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class actions and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

110. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the financial condition, business, operations, and management of the Company;

- whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- whether the Individual Defendants caused the Company to issue false and misleading SEC filings and public statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading SEC filings and public statements during the Class Period;
- whether the prices of Ocular securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what the proper measure of damages is.

111. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to redress individually the wrongs done to them. There will be no difficulty in the management of this action as a class action.

112. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;

- Ocular securities are traded in an efficient market;
- the Company's securities were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ, and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiffs and members of the Class purchased and/or sold Ocular securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

113. Based upon the foregoing, Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

114. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

IX. COUNT ONE

Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

115. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

116. This Count is asserted against the Company and the Individual Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

117. During the Class Period, the Company and the Individual Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

118. The Company and the Individual Defendants violated § 10(b) of the 1934 Act and Rule 10b-5 in that they:

- employed devices, schemes and artifices to defraud;
- made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- engaged in acts, practices and a course of business that operated as a fraud or deceit upon Plaintiffs and others similarly situated in connection with their purchases of Ocular securities during the Class Period.

119. The Company and the Individual Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated in, or acquiesced in, the issuance or dissemination of such statements or documents as primary violations of the securities laws. These Defendants, by virtue of their receipt of information

reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein.

120. The Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiffs and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other personnel of the Company to members of the investing public, including Plaintiffs and the Class.

121. As a result of the foregoing, the market price of Ocular securities was artificially inflated during the Class Period. In ignorance of the falsity of the Company's and the Individual Defendants' statements, Plaintiffs and the other members of the Class relied on the statements described above and/or the integrity of the market price of Ocular securities during the Class Period in purchasing Ocular securities at prices that were artificially inflated as a result of the Company's and the Individual Defendants' false and misleading statements.

122. Had Plaintiffs and the other members of the Class been aware that the market price of Ocular securities had been artificially and falsely inflated by the Company's and the Individual Defendants' misleading statements and by the material adverse information that the Company and the Individual Defendants did not disclose, they would not have purchased Ocular securities at the artificially inflated prices at which they did, or at all.

123. As a result of the wrongful conduct alleged herein, Plaintiffs and other members of the Class have suffered damages in an amount to be established at trial.

124. By reason of the foregoing, the Company and the Individual Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the Plaintiffs and the other members of the Class for substantial damages which they suffered in connection with their purchases of Ocular securities during the Class Period.

X. COUNT TWO

Violation of Section 20(a) of The Exchange Act Against the Individual Defendants

125. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

126. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information regarding the Company's business practices.

127. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the Company's financial condition and results of operations, and to correct promptly any public statements issued by the Company which had become materially false or misleading.

128. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which the Company disseminated in the marketplace during the Class Period. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause the Company to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning

of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Ocular securities.

129. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, the Company to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiffs and the other members of the Class complain.

130. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiffs and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

XII. JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury in this Action.

Dated: May 7, 2018

Respectfully submitted,

POMERANTZ LLP

/s/ Austin P. Van

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was filed with the Court's electronic case filing (ECF) system on May 7, 2018, which caused an electronic copy of this document to be served on all counsel of record in this matter.

/s/ Austin P. Van
Austin P. Van